EC-2000-007
IV-D-112

Gustafson

27 February 2002 **Via Fed Ex**
U.S. Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460

Subject: Gustafson LLC comments/Docket Number EC-2000-007

To Whom It May Concern:

Gustafson LLC has reviewed the EPA's proposed Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), which was published in the 66 Federal Register 46162 (31 August 2001). We would like to present the attached list of suggestions that we believe should be addressed concerning these proposed regulations.

Sue Shen, Director, NAFTA Regulatory and Government Affairs, would be happy to discuss our recommendations. She may be contacted at (972) 985-5637.

Sincerely,

Pat McFadden
Senior GLP Study Coordinator

cc: Sue-Chi Shen
Dennis McFadden
Shawn Billmyre
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Attachment

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SUMMARY

EPA's Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), published in the Federal Register on 31 August 2001 (Vol. 66 FR No. 170, pp. 46162-46194), is described by EPA as 'allowing' electronic reporting and electronic record-keeping for 40 CFR regulated entities, as prescribed by the Government Paperwork Elimination Act (GPEA) [Public Law 105- 277].

In keeping with the GPEA requirements, EPA states in the summary to CROMERRR, "Under today's proposal, electronic document submission or electronic record-keeping will be totally **voluntary**...." We believe that the EPA's assertion that CROMERRR's record-keeping requirements are "voluntary" may be true in the sense that regulated entities are not required to keep records electronically. However, many analytical systems used in our studies require electronic record-keeping. It is not a viable business decision to revert to paper. We believe that the "voluntary" aspect of CROMERRR exists only in theory. The stringent criteria for maintaining electronic records in a 'one size fits all' manner, whereby all electronic records maintained for the purposes of meeting Title 40 program requirements must meet the same criteria, whether an environmental monitoring system, an analytical data collection system, a policy record, or an indexing tool, impose added cost and burden to regulated entities, rather than removing obstacles to electronic record-keeping. Perhaps consideration could be given to classifying electronic record-keeping systems in some way that takes into account the purpose of the record, whether data are manipulated or processed in the system, and whether the data collection is a continual monitoring process or a process with finite endpoints. In the area of archiving records for the entire record retention period, we suggest that EPA reevaluate existing record retention times. The current record retention period for FIFRA registration data can be as long as thirty years, if not longer. Given the rate of technological advances, this would require numerous costly data migration exercises that would place a significant financial burden on regulated entities. Additionally, we recommend that EPA acknowledge the need for industry and the Agency to work toward acceptable solutions for archiving without penalizing regulated entities for not having achieved compliance with this requirement.

We would recommend EPA to decouple the record-keeping portion of the proposed rule from the reporting portion to allow for adequate consideration of existing technology, record retention requirements, the pervasiveness of electronic recordkeeping, and the degree of security and control required based on the type and impact of the electronic records. This decoupling would allow EPA to enable electronic reporting, as mandated by the GPEA, while re-evaluating the electronic record-keeping requirements.

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DISCUSSION

Preamble header lists the following: 40 CFR Parts 3, 51, 60, 63, 70, 123, 142, 145, 162, 233,
257, 258, 271, 281, 403, 501,745, and 763.

The Preamble Summary states "EPA will only begin to accept direct submission of an electronic document ... and will only begin to allow electronic records to satisfy a specific EPA record-keeping requirement once EPA has provided public notice stating that such documents and records will satisfy the identified requirement."

§3.2 (b) Electronic record-keeping...: "An electronic record may satisfy any requirement in this Title provided that (1) it satisfies the requirements of 3.100 and (2) that EPA has published a notice in the Federal Register announcing that EPA is prepared to recognize electronic records under the named Part or Subpart of this Title."

Comment: Some systems (such as analytical equipment) require the maintenance of electronic records. A literal reading of the rule indicates EPA will notify organizations when they can initiate submissions and/or record-keeping, but does not mention if current electronic submissions and record-keeping should continue. Please clarify the CROMERRR status for electronic record-keeping and submissions currently in use. Many organizations are already maintaining electronic records for Parts 160 and 169 and need guidance on the status of this practice. Clarification will eliminate confusion as we attempt to comply with CROMERRR standards. Clarification of specific records that will fall under CROMERRR should be addressed.

II. Background

B. How would today's proposal change EPA's current electronic reporting policy? "In terms of electronic signature technology, while we may continue to allow PIN-based approaches, our plan is to emphasize digital signatures based on 'public key infrastructure' (PKI) certificates, given the increasing support for – and acceptance of – PKI for commercial purposes."

Comment: EPA states in the preamble that the proposed rule will be technology neutral. However, by emphasizing PKI as a technological path, EPA appears to be recommending a specific technology. Please clarify EPA's intent concerning PKI, i.e., whether this is an example or if EPA expects to require this approach. Discussions with IT personnel suggest PKI implementation is a major effort with legal ramifications for various issues. Nesting signatures during data collection, report generation and registration submission requires careful planning. Technology is constantly changing for implementing PKI and requires costly software purchase, implementation and support. Corporate purchase and dissemination of PKI certificates is much less costly than the individual plan proposed by EPA and avoids the data ownership issues. The expense is still significant because of the need to renew licenses for PKI software.

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II. E. What information is EPA seeking about electronic reporting and record-keeping proposals? "EPA is seeking comment whether today's proposal will make electronic reporting and record-keeping a practical and attractive option for smaller regulated entities, especially small business."

Comment 1: Small companies that perform work under EPA FIFRA GLPs have embraced electronic systems for data collection and recording in order to utilize modern methods and to increase productivity. If these systems are not CROMERRR compliant, or are not capable of becoming CROMERRR compliant, these small companies must incur additional costs for equipment upgrades, or return to paper-based systems. In fact, some analytical methods cannot be performed without the use of computer-based systems. In such cases, there is no "paper option." These alternatives, lack of an equivalent paper-based system and additional equipment costs, create significant business obstacles for small companies. Electronic record-keeping requirements present a significant challenge for small business.

Comment 2: Since this is a "voluntary" rule, does industry have the option of collecting data using electronic means, printing a hard copy, and defining the printout as the raw data? We recommend that this practice be allowable as an alternative in situations where it makes sense. Since the reality is that electronic capture of data is a standard practice, if industry is not permitted to define the printout from electronic capture as the raw data, the "voluntary" aspect of CROMERRR no longer applies. This will impose an unreasonable burden on industry, as records for many 40 CFR programs are currently captured electronically, while the data may be printed out and archived as hard copy.

III. C. EPA believes that receipt of electronically transmitted CBI requires considerably stronger security measures than the initial version of CDX may be able to support, including provisions for encryption.

Comment: We believe that confidential business information (CBI) should be transmitted only if the CDX includes provisions for encryption. Furthermore, we believe that all information transmitted over the internet should be encrypted. Without encryption, any information transmitted over the internet will not be secure. One of the key goals stated in this legislation is accountability (trustworthy, reliable and generally equivalent to paper records) for submitted data. Individuals and organizations cannot be held accountable for unsecured data submitted over the internet unencrypted. Hence, encryption will have to be in place regardless of whether or not the data are CBI

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III. C. Which documents could be filed electronically? EPA seeks comments and advice on priorities for electronic reporting implementation.
Comment 1: In no instance should the transmission of any data/reports/CBI occur until the CDX system has been adequately tested, evaluated and certified as effective and reliable. We believe that there needs to be a distinction between electronic reporting of data, electronic record-keeping (directed by predicate rules) and confidential business information (CBI). We believe that electronic reporting options should be explored first, independent of electronic record-keeping options, which could be potentially non-voluntary due to predicate rule requirements. EPA should work closely with the EPA FIFRA and TSCA GLP regulated parties to understand fully the amount of data required for submission of documents and only implement electronic reporting after case studies have been completely researched. The interaction between the Agency and the EPA FIFRA and TSCA GLP regulated parties should also explore the timing of data submission and the possibility of re-evaluating the Agency's 'one size fits all' approach. We agree that submission of CBI data is a special category and must only be attempted after careful review and testing of the CDX capabilities, especially for encryption.

V. B. 2 The CDX Registration Process 9. You provide personal and business information that may include some of the following items – your name, home address, e-mail address, social security number, telephone number, credit card number, driver's license information, employer's address, common name of your employer, legal company name of your employer, name and telephone number of your direct manager, and name and telephone number of a human resource contact.
Comment: It may not be feasible (or legal under various state and federal statutes) or reasonable to force individuals to divulge social security numbers, driver license numbers, and personal credit card information. Some individuals may even refuse to provide personal, private and confidential information. Alternative means of verification of identity should be considered. We believe there may be acceptable alternate means of verification that do not include a requirement to divulge personal confidential information for the purpose of identity verification.

VI. E. Unfunded Mandates Reform - Act, paragraph 3 "...this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and ... or in the private sector in any one year...."

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Comment: We ask EPA to re-assess the financial burden of complying with this rule to the entire regulated community. We believe the assertion that the rule is "voluntary" and that this rule will not mandate excess expenditures exists in theory only. The reality is that electronic systems are already being used extensively by the regulated community. In addition, a single facility may be using many different commercially available systems that were not designed to meet the proposed requirements set forth in this rule. Since nearly all of the estimated 1.2 million facilities to be affected by this rule are currently collecting electronic data and creating electronic records a new financial burden analysis is required. In order to comply with this rule, the analysis needs to take into consideration that expenditures in gap and risk analyses, upgrading software, purchasing new systems where others cannot comply and implementing costly migration schemes will place a sizeable burden on industry. If we look to the FDA implementation of 21 CFR Part 11 much has been discussed and written regarding the high cost involved (as much as $100 million to the pharmaceutical industry according to one White Paper, 21 CFR Part 11, Achieving Business Benefits, published by Accenture) in attempting to implement the rule and overcome difficulties that the regulated industry encountered.

§3.3 Definitions, Electronic document
Comment: This definition excludes documents submitted on such magnetic media as diskettes, compact disks or tapes. Does this mean that electronic documents on such media can be submitted, and are not required to comply with the requirements for electronic records as set forth in CROMERRR? Additionally, we recommend changing the term "electronic document" to "electronically submitted document." It is not clear to us what is meant by "exclusion." Is a facility that is excluded from the reporting requirements of CROMERRR also exempt from the record-keeping requirements until such time as an EPA program announces they are prepared to accept electronic reports? Clarification of this and the other issues raised in this comment will reduce potential delays in implementation and remove the burden from the Agency of repeatedly clarifying the issue.

§3.3 Definitions - Electronic record-retention system means any set of apparatus, procedures, software, records or documentation used to retain exact electronic copies of electronic records and electronic documents.

Comment 1: EPA FIFRA, 40 CFR 169.2 (k) concerning data and records requires all "original" data to be maintained for the length of the product registration (which may be

greater than 30 years). We recommend OEI contact the EPA FIFRA office in charge of 40 CFR Part 169 and clarify if the migration of records, meeting CROMERRR's criterion for the migration, will be acceptable as maintaining "original" records and that "original" paper records retention, implicit in 40 CFR Part 169, is nullified by the issuance of CROMERRR. With the data requirements in EPA FIFRA 40 CFR 169.2(k), it is unclear whether migrated data, as implied in CROMERRR, would meet the requirements of 40 CFR Part 169.

Comment 2: We recommend modifying the definition for "electronic record-retention systems" from "used to retain exact electronic copies" to "used to maintain accurate and complete copies." This wording change would clarify the acceptability of migrated data.

§3.20 How will EPA provide notice of changes to the Central Data Exchange?

Comment: We recommend that EPA clarify the backup procedure for the Central Data Exchange and the procedures that will be followed when the system is not operational (down). Although the rule addresses notification of the public for planned changes to the CDX or another EPA electronic document receiving system, it does not indicate how the CDX system will be backed up to protect against the loss of data/reports submitted to EPA. Since electronic documents can only be submitted to this system, there should be procedures in place to let submitters know when the system is down and how submissions should be made during that time period (e.g., use of another receiving system) as well as notification of users when the system is operational again.

§3.100 (a)(1) Generate and maintain accurate and complete electronic records and documents in a form that may not be altered without detection.

Comment: Please clarify any requirements, in addition to a secure audit trail, necessary to satisfy this requirement. According to this section of the rule, an electronic record or electronic document will satisfy a record-keeping requirement of an EPA administered federal environmental program under this title only if it is generated and maintained by an electronic record retention system as specified under this subsection. EPA should clarify any additional controls that it would consider necessary to preserve the integrity of electronic records and documents. The burden and cost to industry in implementing controls should be taken into consideration when determining the need for such practices in the final rule.

§3.100(a)(2) Maintain all electronic records and electronic documents without alteration for the entirety of the required period of record retention;

Comment: It would seem that documents that have already been signed and submitted electronically should be maintained without alteration. However, electronic records may be changed as new data are obtained or when errors have been identified. In the latter case, an audit trail would indicate the changes as specified in §3.100(a)(6).

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§3.100(a)(3) ...accurate and complete copies ....in both human readable and electronic form...for the entirety of the required period of record retention.

Comment 1: EPA FIFRA and TSCA GLP retention times can be very long—e.g., from 10 to about 30 years—whereas FDA GLP (21 CFR Part 58) retention times are 2 to 5 years after submission to FDA in an application for research or marketing permit (in the case of submitting a New Drug Application [NDA], this also can be a very long period of time). We recommend identifying a more liberal approach to records that must be retained for extended periods of time. If migration of electronic records and reports is a solution to recovery over the record retention period, we recommend that OEI undertake a cost benefit analysis, before CROMERRR is finalized, on the impact of migrating data under CROMERRR in EPA FIFRA and TSCA GLP environments. We additionally recommend that EPA consider working with industry representatives, the EPA Office of Enforcement and Compliance, as well as FDA to resolve the issue of long-term recovery of electronic records and reports. This presents a major difference between what is required for FDA's 21 CFR Part 11 on electronic records and what is required of industry by CROMERRR. It may mean that migration of the electronic records and reports, hardware, software, etc., will be required, since retaining obsolete hardware and software is impractical and in some cases impossible for recovery over the extended retention periods required by some EPA or FDA predicate rules. Migration requires major acceptance testing and validation activity. This would be a massive and costly exercise to simply migrate the registration documents for only one chemical entity. Maintaining the meta data during migration is also a very difficult task. The use of data loggers (the most commonly used are Hobos and Stowaways) is widespread in the regulated community. These miniature loggers can log temperature of soil, water, air, relative humidity, barometric pressure and light intensity and can be used for all types of studies, monitoring of weather or building storage conditions, and other scientific applications. Hobos/Stowaways operate on a lithium type battery, which typically lasts around two years at which time it is replaced by the user. Hobos/Stowaways begin logging immediately upon being launched using the software provided with the data logger. Reading out a logger stops the logging cycle, and it is not started again until it has been launched through the computer. To read out the logger, it is connected to the computer and the data are transferred from the Hobo/Stowaway to the computer, usually in a graph. There is no way for someone to read the Hobo/Stowaway data until the data are transferred to this graph. CROMERRR requires that we produce accurate and complete copies of an electronic record and render these copies readily available, in both human readable and electronic form throughout the entire retention period. The retention time may be lengthy, since regulations state that all "original" data should be maintained for the length of the product registration (which may be greater than 30 years). There are several problems inherent to the retention of electronic data generated by Hobos/Stowaways. First, there is the problem of retention of original

electronic raw data. CROMERRR requires that we retain the original electronic raw data; however, in this case, the original raw data are actually in the Hobo/Stowaway unit and is not accessible to anyone. Since these units are battery operated, it is almost impossible to retain this data in its "original" form. If one attempted to archive a Hobo/Stowaway unit, someone would have to replace the batteries on a regular basis so that the data would not be lost due to lack of power. There is no guarantee that the Hobo/Stowaway unit could actually be saved for any length of time since they are designed to transfer data to a graph for human use and not designed for long term data retention. A graph allows for easy retention of the downloaded data in an electronic form. Archiving a data logger would be similar to archiving a thermometer. The thermometer contains original raw data. However, it is useless unless it is recorded in some manner. The temperature is recorded and referred to as the original raw data. With a data logger, the information is downloaded into a spreadsheet and referred to as the original raw data. Second, there is the problem of retaining original data in human readable form. The Hobo unit does not capture original electronic data in a human readable form. The data only becomes "human readable" after it is downloaded into a graph. Until the data are transferred to a graph, there is no way to modify these records. Transferring the records to the graph allows for an audit trail beginning with the downloading of the data from the Hobo/Stowaway. Use of a graph allows the entire electronic record to be preserved without modification in its human readable form and in its electronic form. Third, there is the problem of expenses. A middle of the line Stowaway costs $140. If you archived one of these units, you would then have to replace the original unit with a new unit. This could be very expensive for facilities that use a large number of units. However, the graph download from the data logger can be retained electronically and with very few problems and little expense.

§3.100(a)(4) Provide that any electronic record or electronic document bearing an electronic signature contain the name of the signatory, the date and time of signature, and any information that explains the meaning of the affixed signature;
Comment 1: Please clarify whether all electronic records or only those bearing an electronic signature must contain the specified descriptors. This clarification would explain what is meant by electronic records. Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.
Comment 2: Suggest adding the word "printed" before the phrase "name of signatory." This clarification would explain the required form of the signatory's name.
Comment 3: Please further explain the "time" requirement. Is it hour, or hour and minute, and is the local time where the work is being performed required? This clarification in wording related to the "time" definition would dispel possible confusion about interpretation of this issue.

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§3.100(a)(6) Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records or documents;

Comment 1: Please further explain the "time" requirement. Is it hour, or hour and minute, and is the local time where the work is being performed required? This clarification in wording related to the "time" definition would dispel possible confusion. We recommend the recording of the date and time (hour: minute) local to the operator entries and actions..

Comment 2: Please consider changing the following phrase from "audit trails that automatically..." to "audit trails that, after final approval, automatically..." or to "audit trails for approved electronic records or documents that automatically...." With EPA FIFRA and TSCA GLPs, electronic records and documents have to be "committed" before they become an "officially accepted" electronic record or document. This clarification in wording would allow this process to continue.

§3.100 (a)(9)(ii): Related meta data can be transferred to a new system.

Comment: We recommend that OEI undertake a cost benefit analysis of the impact of migrating data under CROMERRR in EPA FIFRA GLP environments. It is further recommended that the scope, attributes and purpose of the related meta data should be defined. It is likely that migration of electronic records during the entire record retention requirement time will be necessary, since retention periods vary from 10 to about 30 years. This required retention time is considerably greater than for FDA GLP (21 CFR Part 58) records and should be considered when specifying migration and functionality for retained records. The requirement to migrate electronic records would also require validation of the migration system and/or process to assure accuracy, reliability and integrity of the data migration. The cost analysis of the migration requirement should include the cost of validation. Additionally, when migrating electronic records and documents to a new computer system, there is often no reasonable place to receive the meta data from the old system.

§3.100 (a) (9) (iii): Functionality necessary for use of records can be reproduced in a new system;

Comment: It is our contention that the functionality required by archival material is for retrieval of records rather than for use of records. Therefore, we recommend a wording change from "functionality necessary for use of records can be reproduced in a new system" to "functionality necessary for the retrieval of the records can be utilized in a new system." The suggested wording change would be a more accurate reflection of retrieving the records in a new system. Please consider the record retention times (potentially as long as 30 or more years) and the changing technology that might place an unreasonable burden on industry to comply with such a requirement.

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§3.100(b) Computer systems (including hardware and software), controls, and attendant documentation maintained under this Part must be readily available for, and subject to, Agency inspection.

Comment 1: Change the wording to "Current computer systems (including hardware and software), controls, and attendant documentation...." The resources required to archive obsolete software and hardware, and assure that they will function properly at some future date, far outweighs any benefit derived. Please do not require maintenance/retention of legacy systems. The transfer/migration of data from one system to another should be acceptable.

Comment 2: Change control is a desired mechanism for assuring that a system is managed in a way that assures changes to the system have been properly assessed and implemented. Does the term "controls" relate to change control? Please clarify. There is confusion over the meaning of "controls." Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe. Please define "controls" in the definitions section of the regulation or provide a description of what is meant by this term in this section of the regulation.

Comment 3: Legacy systems are not addressed with respect to acceptable electronic records. We recommend that CROMERRR address what to do with legacy computer systems and related records. This could be accomplished by inclusion either in the preamble or in the Rule itself. There will be a tremendous negative economic cost impact if regulated industry must maintain legacy computer systems, for the entire record retention requirement time, as evidence of how electronic records or reports were available at the time of collection.

§3.2000 (a)(1) Have strong and effective protections against unauthorized access to the system;

Comment: More guidance on the minimum requirements needed to meet the "strong and effective" criteria is needed. There may be a broad interpretation across industry of what constitutes "strong and effective protection" against unauthorized system access or foreseeable corruption or system compromise. Furthermore, "strong and effective protection against unauthorized system access" may not be possible under certain types of operating systems (e.g., Windows 98). Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.